

IN THE CLAIMS:

Claims 15, 18, 21-23, 27, 29-32, and 34-38 have been amended herein. New claims 46 and 47 have been added. Please note that all claims currently pending and under consideration in the referenced application are shown below. Please enter these claims as amended. This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1-7. (Previously canceled)

8-9. (Canceled)

10. (Previously presented) A stable non-aqueous single phase biocompatible viscous vehicle which comprises three components selected from the group consisting of solvent, surfactant, and polymer, wherein the components are not the same, wherein the polymer is polyvinylpyrrolidone, the surfactant is glycerol monolaurate, and the solvent is lauryl lactate, and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

11. (Previously presented) A stable non-aqueous single phase biocompatible viscous vehicle which comprises three components selected from the group consisting of solvent, surfactant, and polymer, wherein the components are not the same, wherein the polymer is polyvinylpyrrolidone, the surfactant is polysorbate, and the solvent is lauryl lactate, and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

12-14. (Previously canceled)

15. (Currently amended) A non-aqueous formulation comprising at least one beneficial agent uniformly suspended in a non-aqueous single phase biocompatible viscous

vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the ~~two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise, which formulation can be delivered from an implantable drug delivery system such that the exit shear rate of the formulation is between about 1 and 1×10^{-7} reciprocal second~~ three components selected from the group consisting of solvent, surfactant, and polymer, wherein the polymer is polyvinylpyrrolidone, the surfactant is glycerol monolaurate or polysorbate, and the solvent is lauryl lactate.

16. (Currently amended) A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at body temperature for extended periods of time, the stable non-aqueous viscous protein formulation comprising:

- a) at least one beneficial agent; and
- b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the ~~two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise~~ three components selected from the group consisting of solvent, surfactant, and polymer, wherein the polymer is polyvinylpyrrolidone, the surfactant is glycerol monolaurate or polysorbate, and the solvent is lauryl lactate.

17. (Currently amended) ~~A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising:~~

- ~~a) The stable non-aqueous viscous protein formulation of claim 16, wherein the at least one~~ beneficial agent is present in an amount of at least about 0.1% (w/w) ~~beneficial agent; and~~
- ~~b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two~~

~~components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.~~

18. (Currently amended) ~~A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising:~~

- ~~a) The stable non-aqueous viscous protein formulation of claim 16, wherein the at least one beneficial agent is present in an amount of at least about 10% (w/w) beneficial agent; and~~
- ~~b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.~~

19-20. (Canceled)

21. (Currently amended) A The formulation of claim 16, wherein the stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at 65° C for at least about 2 months, the stable non-aqueous viscous protein formulation comprising:

- ~~a) at least one beneficial agent; and~~
- ~~b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.~~

22. (Currently amended) A The formulation of claim 16, wherein the stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at 37° C for at least about 3 months, the

~~stable non-aqueous viscous protein formulation comprising:~~

- ~~a) at least one beneficial agent; and~~
- ~~b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.~~

23. (Currently amended) A The formulation of claim 16, ~~stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at 37° C for at least about one year, the stable non-aqueous viscous protein formulation comprising:~~

- ~~a) at least one beneficial agent; and~~
- ~~b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.~~

24-26. (Canceled)

27. (Currently amended) A The formulation of claim 16, wherein the ~~stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising:~~

- ~~a) a beneficial agent which has been~~ is ~~dried to a low moisture content prior to incorporation in the stable non-aqueous viscous protein formulation; and~~
- ~~b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about~~

~~1,000 and about 10,000,000 poise.~~

28. (Canceled)

29. (Currently amended) A method for preparing a stable non-aqueous single phase biocompatible viscous vehicle, the method comprising the steps of (1) ~~selecting two components from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same~~ three components selected from the group consisting of solvent, surfactant, and polymer, wherein the polymer is polyvinylpyrrolidone, the surfactant is glycerol monolaurate or polysorbate, and the solvent is lauryl lactate; (2) ~~blending the two~~ three components at elevated temperature under dry conditions to allow the ~~two~~ three components to liquefy; and (3) allowing the ~~liquid from step (2)~~ liquefied components to cool to room temperature such that a stable non-aqueous single phase biocompatible viscous vehicle is formed ~~exhibits a viscosity between about 1,000 and about 10,000,000 poise.~~

30. (Currently amended) ~~A method for preparing a stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the method comprising:~~
~~combining, under dry conditions, a beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and~~ The method of claim 29, wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise;
~~blending the beneficial agent and the vehicle under vacuum at elevated temperature to uniformly suspend the beneficial agent in the vehicle; and~~
~~allowing the formulation to cool to room temperature.~~

31. (Currently amended) ~~A method for preparing a stable non-aqueous viscous~~

~~protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the method comprising:~~

~~combining, under dry conditions, The method of claim 29, wherein the at least one beneficial agent is present in an amount of at least about 0.1% (w/w) of a beneficial agent in a non-aqueous single phase biocompatible viscous vehicle, wherein the vehicle comprises two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise;~~

~~blending the beneficial agent and non-aqueous single phase biocompatible viscous vehicle under vacuum at elevated temperature to uniformly suspend the beneficial agent in the vehicle;~~
~~and~~

~~allowing the formulation to cool to room temperature.~~

32. (Currently amended) ~~A method for preparing a stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the method comprising:~~

~~suspending The method of claim 29, wherein the at least one beneficial agent is present in an amount of at least about 10% (w/w) beneficial agent in a non-aqueous single phase biocompatible viscous vehicle, wherein the vehicle comprises two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise under dry conditions;~~

~~blending the beneficial agent and non-aqueous single phase biocompatible viscous vehicle under vacuum at elevated temperature to uniformly suspend the beneficial agent in the vehicle;~~
~~and~~

~~allowing the formulation to cool to room temperature.~~

33. (Canceled)

34. (Currently amended) ~~A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising: The method of claim 35, wherein administering comprises~~
parenterally administering a ~~therapeutically~~ effective amount of a stable non-aqueous viscous protein formulation ~~capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.~~

35. (Currently amended) A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising:
providing a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising ~~two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise~~ three components selected from the group consisting of solvent, surfactant, and polymer, wherein the polymer is polyvinylpyrrolidone, the surfactant is glycerol monolaurate or polysorbate, and the solvent is lauryl lactate; and
administering the stable non-aqueous viscous protein formulation to a subject, wherein the administering is long-term and continuous.

36. (Currently amended) ~~A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising: providing a stable non-aqueous viscous protein formulation capable of being uniformly~~

~~dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise; and~~
~~administering the stable non-aqueous viscous protein formulation to a subject, wherein the administering comprises-~~ The method of claim 35, wherein administering comprises use of an implantable drug delivery system

37. (Currently amended) ~~A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising: providing a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise; and~~
~~administering the stable non-aqueous viscous protein formulation to a subject, wherein the administering includes-~~ The method of claim 35, wherein administering comprises daily administration of the stable non-aqueous viscous protein formulation and continues for a period selected from the group consisting of about 3 months, about 6 months, and about 12 months.

38. (Currently amended) ~~A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising: providing a stable non-aqueous viscous protein formulation capable of being uniformly~~

~~dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise; and~~

~~administering the stable non-aqueous viscous protein formulation to a subject, wherein the administering is accomplished using an implantable drug delivery system and includes~~
The method of claim 35, wherein administering comprises administering the stable non-aqueous viscous protein formulation daily for a period selected from the group consisting of about 3 months, about 6 months, and about 12 months.

39-45. (Canceled)

46. (New) The formulation of claim 15, wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise, which formulation can be delivered from an implantable drug delivery system such that the exit shear rate of the formulation is between about 1 and 1×10^{-7} reciprocal second.
47. (New) The formulation of claim 16, wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.